RATIONALE FOR THE DEVELOPMENT OF ONTARIO AIR STANDARDS FOR TETRACHLOROETHYLENE

CONSULTATION DRAFT

February 1998

Standards Development Branch
Ontario Ministry of the Environment

Ontario

Executive Summary

The Ontario Ministry of the Environment has identified the need to develop and/or update air quality standards for priority contaminants. The Ministry's Standards Plan which was released in October 1996, identified candidate substances for the development of air standards for the next several years (MOEE, 1996). Tetrachloroethylene was identified as priority for review based both on its pattern of use in Ontario and recent toxicological information published since the existing standard was developed in 1977.

Tetrachloroethylene or perchloroethylene, is a colourless, non-flammable liquid with a sweetish, chloroform like odour. In Canada, the principal uses of tetrachloroethylene are in the dry-cleaning industry and in the cleaning and degreasing of metals. Tetrachloroethylene is also present in a number of house-hold products including paint removers and strippers, water repellants, some specialized aerosol cleaners, fabric finishes, spot removers and wood cleaners. Recent data show that average levels of tetrachloroethylene in Ontario range from 0.1 to 8.5 $\mu g/m^3$ (micrograms per cubic metre), with most values below 2.0 $\mu g/m^3$.

The effects of tetrachloroethylene on human health come from cases of accidental or occupational exposures. High exposures primarily affect the central nervous system although liver and kidney effects have also been reported. Longer-term exposures to tetrachloroethylene have been reported to produce dizziness, headache, nausea and fatigue. Epidemiological studies of workers in the dry-cleaning and laundry industry are inadequate to assess the carcinogenicity of tetrachloroethylene in humans. Carcinogenicity in animals is both species- and gender-specific. This coupled with the lack of adequate epidemiological evidence of carcinogenicity in humans suggests that cancer may not be a critical end-point for human exposure.

Current Ontario air quality standards for tetrachloroethylene are as follows: the half-hour point of impingement standard is 10,000 $\mu g/m^3$ and the 24-hour Ambient Air Quality Criterion is 4,000 $\mu g/m^3$ both of which are based on human health. Recent toxicological information suggests these standards are in need of review.

In developing air quality standards for Ontario, the Ministry of the Environment is reviewing and considering air quality guidelines and standards used by environmental agencies world-wide. Of the criteria reviewed from other agencies, the Tolerable Concentration of 0.36 mg/m^3 (360 $\mu g/m^3$) developed by Health Canada under the *Canadian Environmental Protection Act* was considered to have the most appropriate rationale. This value was used as the basis for recommending revised air quality standards for tetrachloroethylene.

Tetrachloroethylene has been designated as a toxic substance under the *Canadian Environmental Protection Act*. To minimize environmental releases of tetrachloroethylene, Environment Canada has developed a management strategy to reduce its use in dry cleaning and solvent degreasing operations. Under the Strategic Options Process, Environment Canada is targeting a 65%

reduction in use in solvent degreasing by the year 2001, and a 70% reduction in use in dry cleaning by the year 2000.

Based on an assessment of ambient air quality guidelines used in other jurisdiction; the levels of tetrachloroethylene measured in Ontario; modelled ground level concentrations from recent applications for Certificates of Approval; and a review of the recommendations arising from the federal Strategic Options Process on solvent degreasing and dry cleaning, the Ministry is proposing to establish:

- a 24-hour Ambient Air Quality Criterion for tetrachloroethylene of 360 µg/m^3 to replace the existing value of 4,000 µg/m^3;

In light of the reduction strategies for tetrachloroethylene being implemented under the *Canadian Environmental Protection Act*, the Ministry is seeking additional information from stakeholders prior to recommending a revised point of impingement standard for this compound. The Ministry is asking Ontario sources of tetrachloroethylene to assess the emission reductions being achieved through implementation of the recommendations under the *Canadian Environmental Protection Act*. This information will be considered in setting a point of impingement standard for tetrachloroethylene to be implemented on a timetable consistent with the recommendations under the Strategic Options Process.

Table of Contents

1.0 Introduction

Ontario's primary approach to regulating air emissions is based on achieving and maintaining air quality which is protective of human health and the environment. The *Environmental Protection Act* requires all stationary sources which emit or have the potential to emit a contaminant to obtain a Certificate of Approval which outlines the conditions under which the facility can operate.

Compliance with air quality standards and guidelines is one of the criteria used to issue Certificates of Approval. Sources or potential sources of a contaminant are required to control emissions to ensure that the concentration of a contaminant specified by the standard is not exceeded at any point off their property. Dispersion modelling which incorporates detailed engineering calculations is used to relate emission rates from a source to resulting ambient concentrations of a particular contaminant.

The Ministry of the Environment uses a combination of regulatory standards, ambient air quality criteria (AAQCs) and point of impingement (POI) guidelines in reviewing Certificates of Approval (MOEE, 1994a). Point of impingement standards are established under Regulation 346 and can be used directly as enforcement tools as the regulation specifies that a source cannot emit a contaminant at a level which would result in a standard being exceeded at its maximal point of impingement off its property (Section 5(3)). All sources are required to comply with Regulation 346 POI standards unless they are specifically exempted under regulation. As POI standards specified under Regulation 346 apply to all sources, socio-economic issues need to be taken into consideration in their development to ensure that the standards are technically feasible and there is a balance between the benefits and costs of improved ambient air quality.

In addition to POI standards established under Regulation 346, the Ministry also has a larger number of ambient air quality criteria and point of impingement guidelines which are derived from AAQCs. These are used by the Ministry to assess general air quality and the *potential* for causing an adverse effect (MOEE 1994). Like POI standards specified in Regulation 346, point of impingement guidelines are also used in Certificates of Approval to approve new and modified emission sources. Once incorporated into a legal instrument like a Certificate of Approval, point of impingement guidelines are legally binding, however unlike Regulation 346 POI standards, they do not automatically apply to existing sources at the time they are promulgated. AAQCs are normally set at a level not expected to cause adverse human health or environmental effects based on continuous exposure. As such, socio-economic factors such as technical feasibility and costs are not explicitly considered when establishing such limits.

Generally, point of impingement standards and guidelines which employ half-hour averaging times are set such that compliance with the standard or guideline will ensure that the Ambient Air Quality Criterion which is based on longer term averaging periods (e.g. 24-hours) will be met. In certain cases where the effect can occur over short-term exposures, like odours, the 24-hour

Ambient Air Quality Criterion and the half-hour point of impingement standard may have the same value.

The Ontario Ministry of the Environment has identified the need to develop and/or update air guidelines/standards for priority toxic contaminants. The Ministry's Standards Plan which was released in October 1996, identified candidate substances for the development of air standards for the next several years. Tetrachloroethylene was identified as priority for review based both on its pattern of use in Ontario and recent toxicological information published since the existing standard was developed in 1977. This document provides the rationale for recommending a revised AAQC for tetrachloroethylene.

2.0 Review and Evaluation

2.1 General Information

Tetrachloroethylene (C_2Cl_4) is also known as perchloroethylene and commonly known as PERC. It is a clear, colourless liquid with an odour described as ethereal (ACGIH, 1991). Odour thresholds are reported to range from 5 ppm (36 mg/m^3) to 50 ppm (357 mg/m^3) (ACGIH, 1991). The Chemical Abstracts Service (CAS) identification number is 127-18-4, the Registry of Toxic Effects of Chemical Substances (RTECS) number is KX3850000 and the United Nations Hazardous Material number is 1897. Using conditions of 1 atmosphere pressure and 10°C, 1.0 μg/m^3 = 0.140 ppb (1 ppb = 7.14 μg/m^3). Various agencies use conversion factors based on temperatures between 0°C and 25°C. Depending on the exposure temperatures, conversion of units carried out by different agencies may vary slightly.

The known effects on humans have been established primarily from cases in which individuals have been accidentally or occupationally exposed to very high concentrations of tetrachloroethylene. The principal effect of short-term exposure to high levels is on the central nervous system (CNS). Effects on liver and kidneys have also been reported. Long-term exposure may also produce CNS effects such as dizziness, headache, nausea, fatigue and disorientation. Subjects exposed for long periods are reported to have short-term memory deficits, ataxia, irritability, disorientation, sleep disturbances and decreased alcohol tolerance. Such symptoms are sometimes reported to be irreversible. There have also been reports of alterations in liver function (ACGIH, 1991; WHO, 1987). Laboratory animal studies have confirmed CNS effects and adverse effects on the liver
.
The International Agency for Research on Cancer (IARC, 1997) considers the evidence for cancer in humans from exposure to tetrachloroethylene to be inadequate. There have been some cohort studies of laundry workers that suggested excess risk for various tumours, such as lymphosarcomas, leukemias, cancers of the skin, colon, lung, larynx, bladder, liver, urogenital tract and non-Hodgkin's lymphoma. All studies were considered to be inadequate in defining exposure conditions, in the size of the study groups and other confounding factors such as

socioeconomic factors. Tetrachloroethylene was tested for carcinogenicity in mice and rats by oral administration and by inhalation. In mice, it produced liver carcinomas in animals of both sexes. One experiment in rats by oral administration was considered to be inadequate. Exposure of rats to tetrachloroethylene, through inhalation, produced an increased incidence of leukemia; the other experiments by inhalation were considered to be inadequate. Overall, IARC considers that there is sufficient evidence of cancer in animals but only limited evidence for cancer in humans by exposure to tetrachloroethylene (IARC, 1997). On this basis, IARC classifies tetrachloroethylene as a probable human carcinogen (Group 2A)

2.2 Sources and Levels

Maximum levels of tetrachloroethylene measured in Ontario between 1989 and 1993 were 40.7μg/m^3 at Ottawa in 1989 and 55.7 μg/m^3 at Hamilton in 1990. The maximum concentrations measured at other sites were below 3 μg/m^3. Average 24-hour concentrations at sites monitored ranged from 0.1 μg/m^3 to 8.5 μg/m^3 during 1989 to 1991. Most annual average levels were below 2 μg/m^3 (MOEE, 1994a). Data provided by the Lambton Industrial Society indicated that the annual average concentrations in Sarnia and Corunna varied from 0.28 - 0.5 µg/m^3 and 0.55 - 1.22 µg/m^3, respectively between 1992 and 1996 (LIS, 1997). Half-hour average field monitoring data collected between 1993 and 1995 were found to vary from 0.53 µg/m^3 in Kingston to 88 µg/m^3 in Hamilton (detection limit was 0.01 µg/m^3) (MOE, 1998).

In 1978 the average worldwide atmospheric distribution of tetrachloroethylene was reported to be 56 parts per trillion (ppt) (approx. 0.4 µg/m^3) in the Northern Hemisphere and 14 ppt (approx. 0.071 µg/m^3) in the Southern Hemisphere and 35 ppt (0.25 µg/m^3) on a global basis. Urban/industrial areas of the United States showed ranges of 0.3 to 100 ppb (2.1 to 714 µg/m^3) during the late 1970s. In 1986 the median atmospheric concentrations at 577 sites measured in the United States were reported to be 1 µg/m^3. Positive samples reported in 1986 from 7 sites in the Northern and Southern Atlantic states of the United States ranged from 0.05 to 0.27 ppt (0.00036 to 0.0018 µg/m^3) (HSDB, 1996).

According to the World Health Organization (WHO, 1987), maximum short-term average concentrations in urban atmosphere are about 70 µg/m^3, with averages ranging from 1 to 10 µg/m^3. The highest levels were expected to be near dry-cleaning establishments. They reported global background levels to be about 0.2 µg/m^3.

According to the Canadian National Pollutant Release Inventory (NPRI), the total releases of tetrachloroethylene in Canada for the years of 1993, 1994 and 1995 were 185.7, 169.2 and148.9 tonnes, respectively. The total releases to air reported in Ontario from those years were 149, 136.6 and 123.9 tonnes respectively (NPRI 1993, 1994 & 1995). The 1995 NPRI report listed 13 sources of atmospheric release of tetrachloroethylene in Ontario. The majority of these were for degreasing operations. In general, a trend of slight decreases in the release of tetrachloroethylene was observed from 1993 to 1995 across Canada and Ontario.

An analysis of recent applications for Certificates of Approval in Ontario identified 18 sources with emissions of tetrachloroethylene covered by a Certificate. The majority of these cover degreasing or parts-cleaning types of operations, and industrial dry-cleaners. The median Ground Level Concentration (GLC) predicted by Regulation 346 dispersion modelling for all 18 sources was approximately 192.5 $\mu g/m^3$ with 14 of the sources having GLCs above 350 $\mu g/m^3$. Two sources have GLCs above 1000 $\mu g/m^3$, the maximum being 6988 $\mu g/m^3$.

2.3 Review of Existing Air Quality Regulations.

Agency-specific summaries of information concerning air quality guidelines for tetrachloroethylene are presented in the Appendix of this report. A brief summary is presented in Table 1. Both carcinogenic and noncarcinogenic guidelines have been established by these agencies. Among these agencies, the states of California, New York and Massachusetts have developed cancer-risk specific air guidelines which range from 0.02 - 0.17 $\mu g/m^3$ based on a risk level equivalent to 1 in a million. The state of California developed a noncancer chronic inhalation Reference Exposure Level of 35 $\mu g/m^3$. California has recently proposed a chronic inhalation Reference Exposure Level of 40 $\mu g/m^3$ based on the effect of tetrachloroethylene on the alimentary system (California EPA, 1997). The 24-hour noncancer guideline of Massachusetts is 922 $\mu g/m^3$ which was derived from occupational exposure limits. The WHO is proposing a revised guideline of 250 $\mu g/m^3$ (annual averaging time) based on kidney effect in dry cleaning workers (WHO, 1997). Health Canada has developed a noncancer-based Tolerable Concentration (TC) of 360 $\mu g/m^3$, based on effects of inhaled tetrachloroethylene on the liver, kidneys and lungs of animals.

The current Ontario criteria for tetrachloroethylene are human health based. The interim half-hour point of impingement limit is 10,000 $\mu g/m^3$, while the 24-hour Ambient Air Quality Criterion is 4,000 $\mu g/m^3$ (Muller, 1977; MOEE, 1994b).

2.4 Strategic Options for the Management of Tetrachloroethylene under the Canadian Environmental Protection Act (CEPA)

Tetrachloroethylene has been assessed as toxic under the *Canadian Environmental Protection Act* (CEPA). As such, Environment Canada is required to develop options to minimize the environmental release of tetrachloroethylene from all points in its life cycle in order to minimize exposure and the potential environmental and health risk. To develop management options, Environment Canada launched a sectoral Strategic Options Process targeting the use of tetrachloroethylene in the dry cleaning industry and solvent degreasing which accounts for 62% of tetrachloroethylene used in Canada and a much larger percentage of total releases to the

Table 1. Summary of Existing Air Quality Guidelines[1] for Tetrachloroethylene

Agency, Date[2]	Guideline(s)		Comments
USEPA (IRIS) 1991	0.01 mg/kg/day (oral reference dose)		Oral Reference Dose; no inhalation data
California 1993	35 μg/m^3	(inhalation reference exposure level)	inhalation Reference Exposure Level for evaluation of non-cancer risk
	40 µg/m^3	(proposed revision, 1997)	
	1.7 μg/m^3	(lifetime exposure)	$1*10^{-5}$ additional cancer risk
	0.17 μg/m^3	(lifetime exposure)	$1*10^{-6}$ additional cancer risk Both are based on a unit risk of $5.9*10^{-6}$ tumours/(μg/m^3);
WHO 1997	250 μg/m^3	(annual average)	based on avoidance of kidney effects in workers
Netherlands 1987	25 μg/m^3	(target value)	based on risk assessment in Dutch
	240,000 μg/m^3	(maximum acceptable concentration)	
	7.5 μg/m^3	(maximum emission concentration)	
Sweden[3] 1993	680 μg/m^3	(long-term average)	based on an endpoint of cancer and a cancer threshold approach to risk assessment
New York 1990	81,000 μg/m^3	(1-hour average)	1-hour average based on occupational exposure limits;
	0.075 μg/m^3	(annual average)	$1*10^{-6}$ additional cancer risk based on a unit risk of $1.3*10^{-5}$ tumours/µg/m^3)
Massachusetts 1990	922.18 µg/m^3	(24-hour ceiling limit)	24-hour average based on occupational exposure limits;
	0.02 µg/m^3	(allowable ambient limit)	$1*10^{-6}$ additional cancer risk based on a unit risk of $5.52*10^{-5}$ tumours/(µg/m^3)
Health Canada 1996	0.36 mg/m^3	(Tolerable Concentration)	continuous exposure over a lifetime without deleterious effects
Ontario (current) 1977	10,000 μg/m^3	(½-hour point of impingement limit)	point of impingement limiting effect and AAQC limiting effect both based on health
	4,000 μg/m^3	(24-hour limit)	

1. Guidelines in this table can refer to: guidelines, risk-specific concentrations based on cancer potencies, and non-cancer-based reference concentrations.
2. Date here refers to when the health-based guideline background report or original legislative initiative was issued. Sources were the respective agency documents.
3. Proposed by the Swedish Institute of Environmental Medicine.

environment. The process consisted of representatives from government, industry and environmental non-governmental organizations which examined and considered such issues as: the technical feasibility and cost of reducing solvent usage, the benefits of such measures as well as initiatives on-going in other jurisdictions such as the development of the National Emission Standards for Hazardous Air Pollutants by the USEPA.

For solvent degreasing activities, the following emission reduction targets for tetrachloroethylene were recommended (CEPA, 1996):

- a freeze on consumption at a selected baseline level (not to exceed 5.2 kt of trichloroethylene and tetrachloroethylene combined), effective January 1, 1998;
- a 65% reduction in use from the selected baseline by January 1, 2001;
- a further assessment of degreasing technology in 2002 to determine a target for reductions in use beyond 65%.

It was further recommended that these reduction targets be achieved through the development of regulations which establish quotas for tetrachloroethylene and trichloroethylene for individual users. Environment Canada is expected to introduce draft legislation for implementing such a quota-based system for discussion later this year.

For dry cleaning, the Strategic Options Process developed a variety of recommendations which in combination are expected to lead to a 70% reduction in the amount of tetrachloroethylene used in this sector by the year 2000. These recommendations include a phased-in replacement of dry cleaning machines designed to achieve a minimum solvent usage of 10 kilograms of tetrachloroethylene per tonne of clothes cleaned; levies on tetrachloroethylene sold for dry cleaning; operator training on the proper handling and maintenance of equipment; and product stewardship (CEPA, 1996b). Environment Canada is expected to introduce draft legislation for implementing these measures for discussion later this year.

3.0 Development of an Ambient Air Quality Criterion for Ontario

3.1 Discussion of Regulatory Approaches for Tetrachloroethylene

The development of ambient air quality standards and acceptable limits for long-term exposures to tetrachloroethylene is based on two approaches. One approach is for the protection of human health such as injury to the central nervous system, kidneys, lung and liver. The other approach is based on the avoidance of cancer based on inference from animal studies. The two approaches are examined separately.

3.1.1 Regulatory Approaches for Tetrachloroethylene Based on Carcinogenicity Endpoint

Tetrachloroethylene was originally classified as a possible human carcinogen by the International Agency for Research on Cancer (IARC, 1987). IARC has recently reassessed tetrachloroethylene

and now classifies it as a probable human carcinogen (IARC, 1997). The U.S.EPA has withdrawn its carcinogenicity classification for tetrachloroethylene pending review of available data (U.S.EPA, 1997). Under the Canadian Environmental Protection Act tetrachloroethylene was initially classified as possibly carcinogenic to humans (GROUP III), (CEPA, 1993). However, Health Canada has recently revised the classification of tetrachloroethylene and now considers it as "unlikely to be carcinogenic to humans" (Group IV) (Health Canada, 1996).

Epidemiological evidence of tetrachloroethylene carcinogenicity is limited to studies of workers in the dry-cleaning and laundry industries (CEPA, 1993). The data from these studies are considered to be inadequate to assess the carcinogenicity of tetrachloroethylene in humans (IARC, 1987; IARC, 1997; CEPA 1993). A number of studies suggest that tetrachloroethylene is carcinogenic in animals. Inhalation testing has established a link between cancer and exposure to high levels of tetrachloroethylene (CARB, 1991; CEPA, 1993). However, evidence indicates that this carcinogenicity is both species- and gender-specific and is likely to be induced by mechanisms that are not relevant in humans, or at least for which humans are much less sensitive (CEPA, 1993).

California used the results of a 1986 U.S. National Toxicology Program inhalation study as the basis for estimating the carcinogenic risk of tetrachloroethylene to humans. In this bioassay, the tetrachloroethylene was 99.9% pure. Mice were exposed to tetrachloroethylene in two dose groups of 100 ppm (714 mg/m^3) and 200 ppm (1428 mg/m^3). Rats were exposed in two dose groups of 200 ppm (1428 mg/m^3) and 400 ppm (2856 mg/m^3) (NTP, 1986). The Commonwealth of Massachusetts did not consider this study to be appropriate to use, and calculated a unit risk value based on the male and female mouse liver tumours reported a National Cancer Institute (NCI, 1977) gavage study. In this study, the male mice were administered 536 and 1072 mg/kg/day. Female mice were dosed at 386 and 772 mg/kg/day. Massachusetts converted the oral cancer potency to an inhalation unit risk. New York State also used a carcinogenic risk assessment approach, but documentation on the risk assessment is not available (NYDEC, 1991). The unit risks from these three jurisdictions were 5.9×10^{-6} tumours per ($\mu g/m^3$) (California), 5.52×10^{-5} tumours per ($\mu g/m^3$) (Massachusetts), and 1.3×10^{-5} tumours per ($\mu g/m^3$) (New York).

Sweden also considers tetrachloroethylene to be potentially carcinogenic; however, they used a safety factor approach, dividing the lowest observed dose in which cancer was observed in animal studies by a safety factor of 5000 (Fransson and Ahlborg, 1990).

Although a number of agencies in the United States (California, Massachusetts and New York) have developed cancer potency estimates for tetrachloroethylene, recent scientific data on the species-specific nature of tetrachloroethylene carcinogenicity suggests that cancer may not be a critical end-point in humans. Despite the re-classification of tetrachloroethylene as a probable carcinogen to humans by the IARC, no cancer-based risk estimate has been proposed by this agency (IARC, 1997).

3.1.2 Regulatory Approaches for Tetrachloroethylene Based on a Noncarcinogenic Endpoint

The noncancer effects of exposure to tetrachloroethylene have been reviewed by a number of agencies including the World Health Organization (WHO, 1987) the American Conference of Governmental Industrial Hygienists (ACGIH, 1991), the California Air Resources Board (CARB, 1991) and Health Canada (CEPA, 1993).

The WHO (1987) recommended a guideline level of 5 mg/m^3 (24-hour averaging time). This guideline was developed based on the alteration of central nervous system (CNS) function in humans that occurred above 678 mg/m^3, supportive evidence from laboratory animal studies and an uncertainty factor of 100. The WHO has recently proposed a more stringent revision of their air quality guideline for tetrachloroethylene of 250 $\mu g/m^3$ (annual averaging time), based on avoidance of kidney effect for dry cleaning workers (WHO, 1997).

The ACGIH (1991) developed an occupational standard of 339 mg/m^3 to prevent discomfort and subjective complaints. The standard is also considered protective against liver injury. Some states like Massachusetts and New York, have based their short-term limits on the occupational standard extrapolating from non-continuous to continuous exposures.

According to CARB (1991), the no-observed-adverse-effect-level (NOAEL) for chronic inhalation in rats was reported to be 70 ppm (475 mg/m^3) for tetrachloroethylene. However, rats livers were less susceptible than mice to the toxicity of tetrachloroethylene and a NOAEL for mice had not been established. CARB reported that the U.S.EPA oral reference dose of 1×10^{-2} mg/kg corresponds to an ambient air tetrachloroethylene concentration of 35 $\mu g/m^3$, assuming a 70-kg person breathing 20 m^3/day. The California Environmental Protection Agency has recently proposed a revised chronic REL of 40 $\mu g/m^3$. However, details of the proposal are not available (California EPA, 1997).

More recently, Health Canada has developed a TC (Tolerable Concentration) value of 360 $\mu g/m^3$ for tetrachloroethylene based on a lowest-observed-adverse-effect-level (LOAEL) from inhalation studies in animals (Health Canada, 1996). The TC is set to avoid the pulmonary and nephrotoxic effects of tetrachloroethylene. The LOAEL for tetrachloroethylene at an air concentration of 678 mg/m^3 was adjusted for discontinuous exposures to continuous exposures (6/24 hours, 5/7 days) and by applying an uncertainty factor of 1000 to account for intra- and interspecies variations, the use of a LOAEL value rather than a NOAEL, and based on an assumed body weight of 27 kg and a respiration rate of 12 m^3/day for human aged 5 - 11 (this age group has the highest ratio for inhalation volume/body weight), to derive the TC of 360 $\mu g/m^3$.

3.2 Recommendation for an Ambient Air Quality Criterion for Tetrachloroethylene

Recommendations for new or revised Ontario Ambient Air Quality Criteria (AAQC) and point of impingement (POI) standards are based upon a weight-of-evidence evaluation of available information. The classification of tetrachloroethylene as a human carcinogen is equivocal. While

IARC has recently reassessed tetrachloroethylene as a probable human carcinogen from its initial assessment as a possible human carcinogen (IARC, 1997), Health Canada under the *Canadian Environmental Protection Act* now classifies tetrachloroethylene as "unlikely to be carcinogenic in humans" (Health Canada, 1996). Epidemiological evidence of tetrachloroethylene carcinogenicity is limited to studies of workers in the dry-cleaning and laundry industry (IARC, 1987; CEPA, 1993). The data from these studies are considered to be inadequate to assess the carcinogenicity of tetrachloroethylene in humans. While tetrachloroethylene has been shown to be carcinogenic in animals, evidence suggests that this carcinogenicity is both species- and gender-specific (CEPA, 1993). The lack of adequate epidemiological evidence and the species- and gender-specific nature of the animals carcinogenicity data suggest that for tetrachloroethylene, carcinogenicity may not be a critical end-point of concern for humans.

Of the criteria reviewed from other agencies based on a noncarcinogenic end-point, the Tolerable Concentration developed under the *Canadian Environmental Protection Act* by Health Canada was considered to have the most appropriate rationale (Health Canada, 1996). The Tolerable Concentration is based on the lowest observed adverse effect level obtained from inhalation studies on experimental animals and is considered protective against pulmonary and nephrotoxic effects. The application of a variety of safety factors to the LOAEL of 678 mg/m^3 derives a Tolerable Concentration for tetrachloroethylene of 360 $\mu g/m^3$. Health Canada defines the Tolerable Concentration as "airborne concentrations to which it is believed that a person can be exposed without deleterious effects". The Ministry of the Environment recommends that the air quality guideline corresponding to the Tolerable Concentration of 360 $\mu g/m^3$ developed by Health Canada be used as the basis for developing an 24-hour average Ambient Air Quality Criterion for tetrachloroethylene in Ontario.

While the recommended AAQC is based on the prevention of adverse health effects in the human population, the potential effects of tetrachloroethylene on other terrestrial biota including plants, soil microbes and herbivores was also examined. Limited field and laboratory studies suggest that under certain meteorological conditions some conifer species may be sensitive to tetrachloroethylene. If future studies indicate that the proposed air standard for tetrachloroethylene is not protective of tree species in Ontario, then the basis on which the standard is established may need to be reviewed.

4.0 Status of Stakeholder Consultations

In January 1997, the Ministry initiated limited stakeholder consultation on the initial suite of 14 proposed air standards developed under the Standards Plan. During the course of these consultations, written comments were received from several stakeholders expressing concern over the technical ability of Ontario sources to meet the standard proposed. Monitoring or modelling information was not provided to substantiate these concerns however. Stakeholders also expressed concern over the potential conflict between the emission reductions being sought under the Strategic Options Process for Solvent Degreasing and Dry Cleaning and revision of ambient air quality standards for tetrachloroethylene.

As discussed in section 2.4, under the Canadian Environmental Protection Act, the federal government is targeting a 65% reduction in use of tetrachloroethylene in degreasing operations by 2001 with further reductions being explored beyond that date and a 70% reduction in dry-cleaning by 2000. As these sources account for the majority of the tetrachloroethylene used and released to the environment in Ontario, to the Ministry needs to understand the impacts these reductions will have on predicted ground level concentrations for Ontario sources prior to recommending a revised point of impingement standard for this compound. The Ministry is asking Ontario sources to identify what emission reductions are being achieved through implementation of the recommendations arising from the Strategic Options Process and how this will affect predicted ground level concentrations for tetrachloroethylene. This information will be used to set a revised point of impingement standard for tetrachloroethylene to be implemented on a timetable consistent with the recommendations under the Strategic Options Process.

5.0 Recommendations

Based on an assessment of ambient air quality guidelines used in other jurisdictions; the levels of tetrachloroethylene measured in Ontario; modelled ground level concentrations from recent applications for Certificates of Approval; and a review of the recommendations arising from the federal Strategic Options Process on solvent degreasing and dry cleaning, the Ministry is proposing to establish:

- a 24-hour Ambient Air Quality Criterion for tetrachloroethylene of 360 $\mu g/m^3$ to replace the existing value of 4,000 $\mu g/m^3$;

In light of the reduction strategies for tetrachloroethylene being implemented under the Canadian Environmental Protection Act, the Ministry is seeking additional information from stakeholders prior to recommending a revised point of impingement standard for this compound. The Ministry is asking Ontario sources of tetrachloroethylene to assess the emission reductions being achieved through implementation of the recommendations under the Canadian Environmental Protection Act. This information will be considered in setting a point of impingement standard for tetrachloroethylene to be implemented on a timetable consistent with the recommendations under the Strategic Options Process.

6.0 References

ACGIH, 1991. Documentation Of The Threshold Limit Values for Substances in Workroom Air (6th ed.). American Conference of Governmental Industrial Hygienists Inc., Cincinnati, OH.

Buben, J.A. and E.J. O'Flaherty, 1985. Delineation of the role of metabolism in the hepatotoxicity of trichloroethylene and perchloroethylene: a dose-effect study. Toxicol. Appl. Pharmacol., 78:105-122.

California EPA, 1997. Technical support document for the determination of Noncancer Chronic Reference Exposure Levels. Draft for public review. California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, October, 1997. California.

CAPCOA, 1993. Air Toxics "Hot Spots" Program. Revised 1992 Risk Assessment Guidelines. Toxics Committee of the California Air Pollution Control Officers Association.

CARB, 1991. Technical Support Document, Part B: Health Effect of Perchloroethylene, Proposed Identification of Perchloroethylene as a Toxic Air Contaminant, State of California Air Resource Board, Sacramento, CA.

CEPA, 1993. Canadian Environmental Protection Act, Priority Substances List Assessment Report for Tetrachloroethylene.

CEPA, 1996. Strategic Options for the Management of Toxic Substances - Trichloroethylene and Tetrachloroethylene in Solvent Degreasing. Government of Canada, Minister of Supply and Services

CEPA, 1996b. Tetrachloroethylene in the Dry Cleaning Sector; Report of Stakeholder Consultations; Environment Canada, Environmental Protection Directorate

Commonwealth of Massachusetts, 1990. The Chemical Health Effects Assessment Methodology and the Method to Derive Allowable Ambient Limits, Volumes I and II. Commonwealth of Massachusetts, Department of Environmental Protection, Boston, MA.

Commonwealth of Massachusetts, 1995. Massachusetts Threshold Effects Exposure Limits (TEL) and Allowable Ambient Limits (AAL) for Ambient Air. Commonwealth of Massachusetts Executive Office of Environmental Affairs, Department of Environmental Protection, Boston, MA.

Fransson, R. and U.G. Ahlborg, 1990. Medicinska och hgieniska effeketer av diklormetan, trikloreten och terakloeten i omgivningsluft. Institutet för Miljömedicin, Karlolinsk Insitutet, Stockholm, Sverige.

Health Canada 1996. Health-Based Tolerable Daily Intakes/Concentrations and Tumorigenic Doses/Concentrations for Priority Substances. Government of Canada, Minister of Supply and Services

Hattis, D., S. Tuler, L. Finkelstein and Z.A. Luo, 1987. A pharmacokinetic/ mechanism-based analysis of the carcinogenic risk of perchloroethylene. Report for Center for Technology, Policy and Industrial Development (CTPID 86-7). Massachusetts Institute for Technology, Cambridge, MA.

HSDB (Hazardous Substances Database), 1996. CISTI, Ottawa, Ont.

IARC, 1987. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans. Genetic and Related Effects: An Updating of Selected IARC Monographs from Volumes 1 to 42. Supplement 6. International Agency for Research on Cancer, Lyon, France. 697+ p.

IARC, 1997. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans. Vol. **63**:159. International Agency for Research on Cancer, Lyon, France

LIS, 1997. T.S. Munro, personal communications, Lambton Industrial Society: LIS Ambient Data Summary. Ontario

McConnell, E.E., 1995. Historical review of the rodent bioassay and future directions. Reg. Toxicol. Pharmacol. 21:38-43.

MOEE, 1994a. Windsor Air Quality Study: Health Effects Assessment. Appendices 1-24. Ontario Ministry of the Environment and Energy, Toronto, Ont.

MOEE, 1994b. Summary of Point of Impingement Standards, Ambient Air Quality Criteria (AAQC) and Approvals Screening Levels (ASL). Standards Development Branch, Ontario Ministry of the Environment and Energy, Toronto, Ont.

MOEE, 1996. Three Year Plan for Standards-Setting. Ministry of Environment and Energy, Toronto, Ontario.

MOE, 1998. Personal communications (N. Karellas), Ontarion Ministry of the Environment, Ontario.

Muller, J., 1977. Recommended 24-h Ambient Air Criterion for Tetrachloroethylene. Ontario Ministry of Labour, Toronto Ont. 20 p.

NCI (National Cancer Institute), 1977. Bioassay of tetrachloroethylene for possible carcinogenicity. NCI-TR-13, DHEW, Washington, DC.

NeR Staff Office, 1992. Netherlands Emission Regulations - Air. Netherlands Emission Regulations Staff Office, Bilthoven, The Netherlands. 81 p. + Appendices.

Netherlands MHSPE, 1994. Environmental Quality Objectives in The Netherlands. A review of environmental quality objectives and their policy framework in The Netherlands. Risk Assessment and Environmental Quality Division, Ministry of Housing, Spatial Planning and the Environment, The Hague, The Netherlands. 465 p.

NPRI, 1993. The National Pollutant Release Inventory: Summary Report of 1993. Canadian Environmental Protection Act. Environment Canada.

NPRI, 1994. The National Pollutant Release Inventory: Summary Report and Database of 1994. Canadian Environmental Protection Act. Environment Canada.

NPRI, 1995. The National Pollutant Release Inventory: Summary Report and Database of 1995. Canadian Environmental Protection Act. Environment Canada.

NTP (National Toxicology Program), 1986. NTP Technical Report on the Toxicology and Carcinogenesis Studies of Tetrachloroethylene (Perchloroethylene) (CAS No. 1278-18-4) in F344/N rats and B6C3F1 mice (Inhalation Studies). Research Triangle Park, N.C. NTP TR 311, NIH Publication No. 86-2567.

NYDEC, 1991. New York State Air Guideline -1. Guidelines for the Control of Toxic Ambient Air Contaminants. Draft. New York State Department of Environmental Conservation, Albany, NY. 20 p. + Appendices.

USEPA, 1985. Human Health Assessment for Tetrachloroethylene (Perchloroethylene). NTIS, Springfield, VA.

USEPA, 1997. Integrated Risk Information System (IRIS) Database. U.S. Environmental Protection Agency, Washington, DC.

Victorin, K., 1993. Health effects of urban air pollutants: guideline values and conditions in Sweden. Chemosphere, 27:1691-1706.

WHO, 1987. Air Quality Guidelines for Europe. WHO Regional Publications, European Series No. 23. World Health Organization, Regional Office for Europe, Copenhagen, Denmark. 426p.

WHO, 1997. Updating and Revision of the Air Quality Guidelines for Europe: Report on a WHO Working Group on Volatile Organic Compounds. October, 1995, The World Health Organization, Brussels, Belgium.

7.0 Appendix: Agency-Specific Reviews of Air Quality Guidelines

7.1 Agency-Specific Summary: Federal Government of the United States

1. Name of Chemical: tetrachloroethylene

2. Agency: U.S. Environmental Protection Agency

3. Guideline Value(s):
The only information on tetrachloroethylene is an oral reference dose. The oral reference dose is 0.01 mg/kg/day.

4. Application:
IRIS was developed as a source of consistent risk information on chemicals for use in decision-making and regulatory activities. However, values derived and presented in IRIS do not represent guidelines or standards, in and of themselves. IRIS also contains a summary of current American government regulatory actions under various legislative mandates.

5. Documentation Available:
USEPA, 1997. Integrated Risk Information System (IRIS) Database. U.S. Environmental Protection Agency, Washington, DC.

Key Reference(s):
Buben, J.A. and E.J. O'Flaherty, 1985. Delineation of the role of metabolism in the hepatotoxicity of trichloroethylene and perchloroethylene: a dose-effect study. Toxicol. Appl. Pharmacol., 78:105-122.

6. Peer Review Process and Public Consultation:
Peer-reviewed scientific research data, analyses and evaluations from various sources, including a variety of public and government agencies from around the world and the published scientific literature, were employed in the development of these values. Both the general assessment methodologies and the chemical-specific information found in IRIS undergo extensive scientific and policy reviews, within both the EPA and other science-based U.S. regulatory agencies. Information in IRIS is put forward for use after the results of the public review and comments on draft documents/information have been addressed.

7. Status of Guideline:
No guideline exists. The risk estimate discussed is for respiratory exposure from air only.

8. Key Risk Assessment Considerations:
The USEPA used a study by Buben and O'Flaherty (1985) to calculate an oral reference dose for tetrachloroethylene. Buben and O'Flaherty exposed Swiss-Cox mice to tetrachloroethylene in corn oil by gavage at doses of 0, 20, 100, 200, 500, 1500 and 2000 mg/kg, 5 days/week for 6 weeks. Liver toxicity was evaluated by several parameters, including liver weight/body weight ratio, hepatic triglyceride concentration, DNA content, histopathological evaluation, and serum enzyme

levels. Increased liver triglycerides were first observed in mice treated with 100 mg/kg. Liver weight/body weight ratios were significantly higher than controls for animals treated with 100 mg/kg. At higher doses, hepatotoxic effects included decreased DNA content, increased SGPT, decreased levels of G6P and hepatocellular necrosis, degeneration and polyploidy. The dose group of 20 mg/kg was identified as the no-observable-adverse-effect-level. It was adjusted to 14 mg/kg/day to account for the treatment schedule (5 days/week). An uncertainty factor of 1000 was applied to results from multiplying factors of 10 to account for intraspecies variability, interspecies variability and extrapolation of a subchronic effect level to its chronic equivalent.

A NOEL of 14 mg/kg/day was established in a second study as well (Hayes *et al*., 1986). Groups of 20 Sprague-Dawley rats of both sexes were administered doses of 14, 400 or 1400 mg/kg/day in drinking water. Males in the high-dose group and females in the two highest groups exhibited depressed body weights. Equivocal evidence of hepatotoxicity (increased liver and kidney weight/body weight ratios) were also observed at the higher doses.

9. Key Risk Management Considerations:
None, since no guideline for ambient air exists.

10. Multimedia Considerations of Guidelines:
None are reported.

11. Other Relevant Factors:
No information

7.2 Agency-Specific Summary: State of California

1. Name of Chemical: tetrachloroethylene

2. Agency: State of California (Office of Environmental Health Hazard)

3. Guideline Value(s):
The State of California states that the unit risk of 5.9 x 10^{-6} tumours per ($\mu g/m^3$) is to be used for evaluation of cancer risks (CAPCOA, 1993). At risk levels of 10^{-5} and 10^{-6} this corresponds to risk specific air concentrations of tetrachloroethylene of 1.7 $\mu g/m^3$ and 0.17 $\mu g/m^3$ respectively. The Reference Exposure Level of 35 $\mu g/m^3$ is to be used for non-cancer risk assessment. The California EPA has recently proposed to revise the chronic inhalation REL to 40 $\mu g/m^3$, based on effects on the alimentary system.

4. Application:
"The intent of the Committee in developing the guideline was to provide risk assessment procedures for use in the Air Toxics 'Hot Spots' Program." (CAPCOA, 1993). This program is based on a California State law: the Air Toxics 'Hot Spots' Information and Assessment Act of 1987 (Health and Safety Code Section 44360 *et seq*.). The act specifies how local Air Pollution Control Districts determine which facilities in their areas will prepare health risk assessments, how such health risk assessments should be prepared and how the results are to be prioritized. These guidelines were prepared to provide consistent risk assessment methods and report presentation to enable: 1) comparisons between facilities, 2) expeditious review of risk assessments by reviewing agencies, and 3) minimal revisions and resubmittals of risk assessments. The various health-based exposure levels developed for and employed in this program should not be employed outside the framework of the program. That is to say, the State of California does not consider them to be general, independent, legally enforceable air quality guidelines or limit values at this time.

5. Documentation Available:
CAPCOA, 1993. CAPCOA Air Toxics "Hot Spots" Program. Revised 1992 Risk Assessment Guidelines. Toxics Committee of the California Air Pollution Control Officers Association.

CARB, 1991. Technical Support Document, Part B: Health Effect of Perchloroethylene, Proposed Identification of Perchloroethylene as a Toxic Air Contaminant, State of California Air Resource Board, Sacramento, CA.

California EPA, 1997. Technical support document for the determination of Noncancer Chronic Reference Exposure Levels. Draft for public review. California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, October, 1997. California

Key Reference(s):
Hattis, D., S. Tuler, L. Finkelstein and Z.A. Luo, 1987. A pharmacokinetic/mechanism-based analysis of the carcinogenic risk of perchloroethylene. Report for Center for Technology, Policy

and Industrial Development (CTPID 86-7). Massachusetts Institute of Technology, Cambridge, MA, as cited in CARB, 1991.

NTP (National Toxicology Program), 1986. NTP Technical Report on the Toxicology and Carcinogenesis Studies of Tetrachloroethylene (Perchloroethylene) (CAS No. 1278-18-4) in F344/N rats and B6C3F1 mice (Inhalation Studies). Research Triangle Park, N.C. NTP TR 311, NIH Publication No. 86-2567, as cited in CARB, 1991.

6. Peer Review Process and Public Consultation:
Cancer potency slope factors and acute and chronic reference levels were prepared by the California Office of Environmental Health Hazard Assessment (OEHHA), and these, as well as the exposure and health assessments, have undergone public review and comment prior to finalization. Peer-reviewed scientific research data were employed in the development of these values. Under the CAPCOA risk assessment process, each assessment is site-specific, and public notice to all exposed individuals is required when the screening process determines that a significant health risk is associated with emissions from a facility. Public input was obtained in identifying and ranking areas and facilities for risk assessment screening and, according to the documentation, additional input is expected as the process moves forward.

7. Status of Guideline:
Current, but updates are possible, with new California risk assessment guidelines being considered in the California Senate.

8. Key Risk Assessment Considerations:
According to CARB (1991), the no-observed-adverse-effect-level (NOAEL) for chronic inhalation in rats was reported to be 70 ppm tetrachloroethylene. However, rats were less susceptible than mice to hepatotoxicity and a NOAEL for mice had not been established. CARB reported that the USEPA oral reference dose of 1×10^{-2} mg/kg (unreferenced) corresponds to an ambient air tetrachloroethylene concentration of 35 $\mu g/m^3$, assuming a 70-kg person breathing 20 m^3/day. This level is above current ambient air concentrations in California, and CARB did not expect that adverse health effects from acute or chronic exposure to ambient air would occur. The California EPA has recently proposed to revise the chronic inhalation REL to 40 $\mu g/m^3$, based on effects on the alimentary system. Detailed information on this proposal is not available.

CARB (1991) considered tetrachloroethylene (perchloroethylene) to be a probable human carcinogen because of sufficient evidence of carcinogenicity in laboratory animal studies and inadequate evidence from human studies. Results from the 1986 NTP inhalation study were used as the basis for estimating the carcinogenic risk of tetrachloroethylene to humans. In this bioassay, tetrachloroethylene was 99.9% pure. Rats and mice were exposed 6 hour per day, 5 days per week for 103 weeks. The mice were exposed in two dose groups of 100 and 200 ppm, the rats in two dose groups of 200 and 400 ppm (NTP, 1986). The metabolized dose, adjusted to continuous lifetime exposure was, used to calculate the carcinogenic potency. The upper bound of metabolism can be assumed to be 25% (Hattis *et al*., 1987). The upper range of metabolism at low concentrations was assumed to be as high as 73% (Hattis *et al*, 1987; Bois *et al*., 1990; Bogen and McKone, 1987, 1988). The Crump multistage polynomial model was chosen for low-

dose extrapolation. The upper bound of extra cancer cases predicted from lifetime exposure to 1 ppb (6.78 µg/m^3) was estimated to be from 2 to 72 x 10^{-6} tumours. This represents the upper limit of plausible excess cancer cases and corresponds to a range of unit risks of 0.3 to 10.6 x 10^{-6} tumours/(µg/m^3) of tetrachloroethylene lifetime exposure. According to CARB, considering the quality of the studies used and the importance of incorporating a 25% estimate of metabolism in humans, the best value for the 95% upper confidence limit was 54 x 10^{-6} (ppb) (unit risk of 7.9 x 10^{-6}/(µg/m^3)). The unit risk could be three times higher if the plausible upper limit on human metabolism were used (CARB, 1991).

9. Key Risk Management Considerations:
The exposure guidelines were prepared for both non-cancer- and cancer-based endpoints. The cancer-based value is to be used in a screening risk assessment to determine the maximum offsite cancer risk for the exposed human population. The process is not readily comparable to the air quality guideline approach to non-carcinogens. The non-cancer guidelines are based on the most sensitive adverse health effect reported in the scientific literature and are designed to protect the most sensitive individuals in the population.

There are options for addressing the possible economic impacts of controlling tetrachloroethylene emissions. It appears that the options are under local control and are based on local risk and socio-economic analyses, as well as public workshops and hearings. The enforcement mechanism is via operating permits. Thus, the process is primarily directed towards site-specific evaluations and development of further regulatory tools, rather than being enforceable levels in and of themselves.

10. Multimedia Considerations of Guidelines:
In the exposure modelling process, non-inhalation pathways should be considered for a number of substances (specified in Table III-5 in CAPCOA, 1993). Tetrachloroethylene is not one of the substances that require non-inhalation modelling. In the California EPA exposure and health assessments it was acknowledged that exposure pathways other than air (e.g., water and food) were possible but that, due the lack of quantitative information and the predominance of airborne exposure, other exposure pathways were not considered in the development of the guideline.

11. Other Relevant Factors:
California considers that the mutagenic potential of tetrachloroethylene has not been clearly established; but the positive results in genotoxicity assays with tetrachloroethylene indicate a possible interaction with DNA and the potential for tetrachloroethylene to be an active genotoxin.

7.3 Agency-Specific Summary: World Health Organization

1. Name of Chemical: tetrachloroethylene

2. Agency: World Health Organization

3. Guideline Value(s):
The level of 5,000 $\mu g/m^3$ (24-hour average) was recommended. The WHO has proposed to revise this guideline to 250 $\mu g/m^3$ (annual average).

4. Application:
"The guidelines are intended to provide background information and guidance to governments in making risk management decisions, particularly in setting standards. It should be strongly emphasized that the guideline values are not to be regarded as standards in themselves" (WHO, 1987, pg. xiii)

5. Documentation Available:
WHO, 1987. Air Quality Guidelines for Europe. WHO Regional Publications, European Series No. 23. World Health Organization, Regional Office for Europe, Copenhagen, Denmark. 426p.

WHO, 1997. Updating and Revision of the Air Quality Guidelines for Europe: Report on a WHO Working Group on Volatile Organic Compounds. October, 1995, The World Health Organization, Brussels, Belgium.

Key Reference(s):
WHO, 1984. Tetrachloroethylene. World Health Organization, Geneva, Switzerland, as cited in WHO, 1987.

6. Peer Review Process and Public Consultation:
Scientific background documents were prepared by experts and submitted to working groups consisting of international experts. After a series of meetings and internal and external reviews by experts and representatives of Member States of the Region, the resultant conclusions and recommendations were presented at a final meeting, where they were adopted by consensus of the representatives. In addition, peer-reviewed scientific research data were employed in the development of these documents.

7. Status of Guideline:
No information

8. Key Risk Assessment Considerations:
Available data on man, together with supportive evidence from laboratory animal studies suggest that short-term exposure to 678 mg/m^3 represents a likely threshold for nongenotoxic adverse effects (e.g., central nervous system disturbances and transient liver damage). A no-observed-effect-level of 136 mg/m^3 has been identified for man in short-term repeated exposure (WHO, 1984). There are no data for a no-observed-adverse-effect-level in man for long-term exposure.

However, while tetrachloroethylene is generally considered to be hepatotoxic and nephrotoxic in laboratory animals, the evidence regarding humans suggests that environmental levels pose no serious health problem. A protection factor of 100 applied to the threshold for of 678 mg/m^3 in short-term observations is considered appropriate. A guideline value of 5 mg/m^3 over a 24-hour period is recommended. The odour detection threshold is 8 mg/m^3. The WHO has recently proposed a more stringent revision of their air quality guideline for tetrachloroethylene of 250 $\mu g/m^3$ (annual averaging time), based on avoidance of kidney effects for dry cleaning workers (WHO, 1997). This revised guideline value is derived from a long-term LOAEL of 102 mg/m^3 in dry cleaning workers. This LOAEL was divided by a factor of 4.2 to adjust for 40-work week exposures to continuous exposure and then further divided by an uncertainty factor of 100 to account for the use of an LOAEL and for intraspecies variation.

9. Key Risk Management Considerations:
No information

10. Multimedia Considerations of Guidelines:
Human exposure from air, drinking water and diet was considered in the evaluation, but this did not specifically contribute to the determination of the final guideline value.

11. Other Relevant Factors:
The guideline value is applicable to both indoor and outdoor situations.

7.4 Agency-Specific Summary: The Netherlands

1. Name of Chemical: tetrachloroethylene

2. Agency: Netherlands Ministry of Housing, Spatial Planning and the Environment

3. Guideline Value(s):
The maximum acceptable concentration (MAC) is 240 mg/m^3. The maximum emission concentration (MIC) for airborne effluents from point sources is 7.5 μg/m^3. The target value is 25 µg/m^3.

4. Application:
Limit values are non-statutory environmental quality objectives that are considered to be policy guidelines. They should not be exceeded and should be considered as requirements to be met. These effects-oriented guidelines may be used simultaneously with source-oriented emission criteria, although it is the latter that are the primary regulatory mechanism. If effects-oriented guidelines continue to be exceeded, then existing source-oriented emissions criteria will be lowered to bring ambient levels below the effects-oriented guidelines. A maximum acceptable concentration (MAC) is the maximum acceptable concentration of a gas, vapour, or mist of a substance in a workplace.

5. Documentation Available:
Netherlands MHSPE, 1994. Environmental Quality Objectives in The Netherlands. A review of environmental quality objectives and their policy framework in The Netherlands. Risk Assessment and Environmental Quality Division, Ministry of Housing, Spatial Planning and the Environment, The Hague, The Netherlands. 465 p.

NeR Staff Office, 1992. Netherlands Emission Regulations - Air. Netherlands Emission Regulations Staff Office, Bilthoven, The Netherlands. 81 p. + Appendices.

Earlier air criteria documents or more recent integrated criteria documents are available for priority substances such as tetrachloroethylene but only in Dutch.

6. Peer Review Process and Public Consultation:
No specific information on this issue was presented in the available English language documentation.

7. Status of Guideline:
Current

8. Key Risk Assessment Considerations:
No information

9. Key Risk Management Considerations:
National limit values include consideration of environmental, economic and social interests, as well as technical options. Specific information on such details was not presented in the available documentation.

10. Multimedia Considerations of Guidelines:
Multimedia exposure was not considered in the development of the current air guideline limits; however, intercompartmental criteria which address this problem are being developed. A specific schedule for revisions based on this process has not been announced, and tetrachloroethylene is not on the initial list of chemicals to be considered.

11. Other Relevant Factors:
No information

7.5 Agency-Specific Summary: Swedish Institute of Environmental Medicine

1. Name of Chemical: tetrachloroethylene

2. Agency: The values reported below are those recommended by the Swedish Institute of Environmental Medicine. According to Dr. K. Victorin of the Swedish Institute of Environmental Medicine (pers. comm.), no official Swedish air quality guidelines have been promulgated by the Swedish Environmental Protection Agency.

3. Guideline Value(s):
The recommended value from the Institute of Environmental Medicine is a long-term average of 680 $\mu g/m^3$.

4. Application:
Used on an *ad hoc* basis

5. Documentation Available:
Victorin, K., 1993. Health effects of urban air pollutants: guideline values and conditions in Sweden. Chemosphere, 27:1691-1706.

Fransson, R. and U.G. Ahlborg, 1990. Medicinska och hgieniska effeketer av diklormetan, trikloreten och terakloeten i omgivningsluft. Institutet för Miljömedicin, Karlolinsk Insitutet, Stockholm, Sverige.

Although documentation in Swedish has been prepared, only a summary in English is available.

6. Peer Review Process and Public Consultation:
No information was available in the documentation.

7. Status of Guideline:
It has no official status, but has been used on an *ad hoc* basis by Swedish regulators.

8. Key Risk Assessment Considerations:
New data further support the conclusion that tetrachloroethylene has a carcinogenic potential in animals. Tetrachloroethylene lacks a mutagenic potential, which probably means that it mainly causes cancer by epigenetic mechanisms. Because tetrachloroethylene probably exerts its effect through epigenetic mechanisms, a threshold cannot be excluded. Because the effect is serious, a safety factor of 1000 to 5000 is appropriate. Applied to the lowest-observed-effect-level of 200 ppm observed in animal studies, the "medically-based" low risk level is between 40 and 200 ppb. Since 200 ppm does not constitute a NOEL value, the recommended value should be chosen in the lower half of this interval.

9. Key Risk Management Considerations:
It is the intention of the Government of Sweden to phase out chlorinated solvents, primarily through European Cooperation.

10. Multimedia Considerations of Guidelines:
Based on human health considerations for respiration only

11. Other Relevant Factors:
The reason why a safety factor was used and not a linear extrapolating model is the fact that tetrachloroethylene lacks mutagenic properties and thus probably exerts its carcinogenic effect through epigenetic mechanisms. The validity of these models has not be sufficiently substantiated. IEM thus presently recommends the use of the safety factor model.

7.6 Agency-Specific Summary: New York State

1. Name of Chemical: tetrachloroethylene

2. Agency: New York State

3. Guideline Value(s):
The recommended 1-hour average is 81,000 $\mu g/m^3$. The recommended annual average is $7.5*10^{-2}$ $\mu g/m^3$. This long-term guideline was developed using lifetime acceptable individual risk level of 10^{-6} and an estimated unit risk of $1.3*10^{-5}$ tumours per $\mu g/m^3$.

4. Application:
". . . they are primarily intended for use in conjunction with the permitting authority and regulatory concerns found in 6NYCRR Parts 200, 201, 212 and 257." (NYDEC, 1991, p. 1). These regulations refer specifically to construction and operation (Certificate to Operate) permits for any sources of air contamination. Rather than being employed as legally enforceable, ambient air quality standards, the guidelines are to be employed to aid in the regulatory decision-making process. This process includes the classification of chemicals into groups of high, moderate and low toxicity. The regulatory screening process considers the toxicity classification and the emission rate potential from a facility. An air emission dispersion model is also specified in the process to guide regulators in their assessment of chemical emissions from sources of interest. Both long-term and short-term effects are considered.

5. Documentation Available:
NYDEC, 1991. New York State Air Guideline -1. Guidelines for the Control of Toxic Ambient Air Contaminants. Draft. New York State Department of Environmental Conservation, Albany, N.Y. 20 p. + Appendices.

6. Peer Review Process and Public Consultation:
The scientific documents prepared by New York State employed peer reviewed data and models, as well as the professional judgements of its scientific staff. There are opportunities for public comment on guidelines and the guideline development process, but specific information on the process for tetrachloroethylene was not presented in the available documentation.

7. Status of Guideline:
Current

8. Key Risk Assessment Considerations:
New York State (1991) has classified the toxicity of tetrachloroethylene as moderate. Compounds given the designation of moderate are animal oncogens, developmental and reproductive toxicants, genotoxin chemicals and other chemicals posing a health hazard to humans. For compounds in this classification, the short-term guideline was developed by dividing a chosen occupational standard by 4.2. In the case of tetrachloroethylene, New York used the occupational standard of 50 ppm (approximately 304 mg/m^3) (ACGIH, 1991).

The long-term guideline was developed by calculating the air concentration at an acceptable individual risk level of $1*10^{-6}$. They reported that concentration is 0.075 µg/m^3. The unit risk was therefore $1.3*10^{-5}$ tumours per µg/m^3.

9. Key Risk Management Considerations:
A specific computer model and guidance manual are provided for use of the guidelines in impact screening analyses as employed in the permitting process. The latest version of Appendix B of the New York State Air Guide -1 is dated April 4, 1994.

10. Multimedia Considerations of Guidelines:
Considers human airborne exposure only

11. Other Relevant Factors:
None

7.7 Agency-Specific Summary: Commonwealth of Massachusetts

1. Name of Chemical: tetrachloroethylene

2. Agency: Commonwealth of Massachusetts

3. Guideline Value(s):
A 24-hour ceiling limit is 922.18 $\mu g/m^3$, based on the threshold effects exposure limit (TEL). The allowable ambient limit (AAL) is 0.02 $\mu g/m^3$ for an annual (1 year) averaging time and is based on consideration of carcinogenic effects at risk level of 10^{-6} for a 70-year lifetime.

4. Application:
". . . the Division of Air Quality Control, which is responsible for implementing the Department's air programs, plans to employ the AALs in the permitting, compliance, and enforcement components of the Commonwealth's air program in general, and the air toxics program in particular." (Commonwealth of Massachusetts, 1990, Volume 1, pg. ix). The primary goal is to "protect the public health and welfare from any air contaminant causing known or potentially injurious effects." The ambient air levels developed in this process should not be considered legally enforceable air quality standards, since they deal only with health-related matters and contain no consideration of technological, economic or enforcement concerns. Rather, they should be employed as guidelines in the development of subsequent regulatory action which does contain a broad consideration of all relevant concerns.

5. Documentation Available:
Commonwealth of Massachusetts, 1990. The Chemical Health Effects Assessment Methodology and the Method to Derive Allowable Ambient Limits, Volumes I and II. Commonwealth of Massachusetts, Department of Environmental Protection, Boston, MA.

Commonwealth of Massachusetts, 1995. Massachusetts Threshold Effects Exposure Limits (TEL) and Allowable Ambient Limits (AAL) for Ambient Air. Commonwealth of Massachusetts Executive Office of Environmental Affairs, Department of Environmental Protection, Boston, MA.

Key Reference(s):
ACGIH, 1986. Documentation Of The Threshold Limit Values for Substances in Workroom Air (5th ed.). American Conference of Governmental Industrial Hygienists Inc., Cincinnati, OH.

Buben, J.R. and E.J. O'Flaherty, 1985. Delineation of the role of metabolism in the hepatotoxicity of trichloroethylene and perchloroethylene: a dose-effect study. Tox. and Appl. Pharmacol., 78:105-122.

NCI (National Cancer Institute), 1977. Bioassay of tetrachloroethylene for possible carcinogenicity. NCI-TR-13, DHEW, Washington, DC, as cited in ACGIH, 1991.

6. Peer Review Process and Public Consultation:
Peer-reviewed scientific research data, analyses and evaluations from various sources, including a variety of public and government agencies from around the world and the published scientific literature, were employed in the development of these values. Specifically, evidence from the International Agency for Research on Cancer (IARC), the American National Toxicology Program (NTP) and the USEPA was employed. As guidelines, the process used and values generated are not subject to the extensive review and consultation that air quality standards would be subjected to, but external peer reviews were carried out, and public input was solicited through at least two public meetings on the Massachusetts methodology and guideline document (D. Manganaro, Massachusetts Department of Environmental Protection, pers. comm.).

7. Status of Guideline:
Current. Although guideline values are periodically updated, revisions to the current value for tetrachloroethylene are not under consideration (D. Manganaro, Massachusetts Department of Environmental Protection, pers. comm.).

8. Key Risk Assessment Considerations:
The Commonwealth of Massachusetts (1990) has a method for establishing a limit that assumes the compound has a threshold for adverse effects. In the case of tetrachloroethylene, the 1986 ACGIH occupational limit, reported to be 338.9 mg/m^3 (ACGIH, 1986), was divided by several factors that attempt to extrapolate from a worker health-based limit to a public limit that protects children and other sensitive individuals. The uncertainty factor incorporates judgments about the amount of information on the toxicity of the compound, the differences between body sizes and weights between adult males and children and an assumption about the relative contribution of the compound to the total exposure from air. The total uncertainty factor in the case of tetrachloroethylene was 367.5.

The Commonwealth of Massachusetts calculated a unit risk value, based on the male and female mouse liver tumours reported in the NCI (1977) gavage study. The administered dose was used to calculate the dose metabolized to urinary trichloroacetic acid, using data in Buben and O'Flaherty (1985). The metabolized dose was transformed to milligrams of tetrachloroethylene by multiplying the urinary trichloroacetic acid dose by the ratio of the molecular weights (mg trichloroacetic acid*165.8/163.4 = mg tetrachloroethylene). The lifetime average daily dose (LAD) was calculated by multiplying the dose in milligrams of tetrachloroethylene by 5/7 and 78/95. The first factor adjusted for a weekly dose schedule and the second adjusted for the fact that the animals were dosed for 78 weeks and were killed at 95 weeks of age. This adjusted dose was further adjusted to convert the LAD based on urinary metabolites to the total metabolites. This adjustment was made based on factors discussed in USEPA (1985) in which the assumption is made that urinary metabolites are 80% of the total metabolites. This LAD was converted to a human dose, using a surface area scaling factor. The upper 95% confidence interval on the unit oral cancer potency (q*), using a multistage model, was calculated. This value was adjusted for less than lifetime exposure by multiplying it by 104/95, based on a 104-week nominal lifetime for mice and the fact that mice were killed at 95 weeks of age in the NCI study. Finally, the carcinogenic potency for the female mouse was selected as the most appropriate value and the unit risk for oral exposure was considered to be $2.76*10^{-4}$ tumours/(mg/kg)/day

To convert to an inhalation unit risk, it was assumed that the metabolized dose was 70% of the inhaled dose. This was based on the assumption that levels of tetrachloroethylene of concern in the environment will be too low to cause metabolic saturation in any tissue and that the metabolized dose will be equal to 70% of the inhaled dose. According to the Commonwealth of Massachusetts, this is a more reasonable quantitative dose-response assessment for ambient air exposure. The unit risk was reported to be $5.52*10^{-5}$ tumours/($\mu g/m^3$).

9. Key Risk Management Considerations:
The primary objective of the process is the protection of public health. The Massachusetts system uses hazard assessment only and does not use the number of exposed individuals as a criterion for regulatory action. Furthermore, the selection of the AAL is based on the most sensitive effect. The USEPA's cancer unit risk values (USEPA, 1985) and the ACGIH occupational TLV values were adopted for regulation development purposes. For carcinogens, a maximum allowable increase in risk associated with exposure to a chemical was set at one per million (10^{-6}) for a 70-year lifetime.

10. Multimedia Considerations of Guidelines:
A generic allowance was made for contributions from sources other than respiration: "A relative source contribution factor of 20% is also included to account for sources other than air." (Commonwealth of Massachusetts, 1990, pg. viii).

11. Other Relevant Factors:
None